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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,256	11/25/2003	Fiona Patricia Carney	CLV-32783A	6126

31781 7590 04/10/2008

CIBA VISION CORPORATION
PATENT DEPARTMENT
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EXAMINER	
SPIELER, SHAHRZAD	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
04/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,256	CARNEY ET AL.	
	Examiner	Art Unit	
	SHAHRZAD SPIELER	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Publication 2001/0045676 to Winterton, et al in view of US Patent No. 5231801 to Sakuma et al.

The scope of the prior art is such that a medical device comprising a core material which is containing a silicone containing hydrogel and an antimicrobial layer-by-layer (LbL) coating that is not covalently attached to the core material, as disclosed in claim 1 (b). Winterton, et al teaches a method of treating polymeric materials, particularly drawn to forming a coating into a device (see page 1, paragraph 1). The technique for electronic coating of devices discussed in Winterton et al is layer-by-layer (LbL) polymer absorption (see page 1, paragraph 5). In particular, the coating is applied in a multi-step dipping process involving consecutive

application of oppositely charged polyionic materials onto a material, a bi-layer, which is essentially non covalent (see page 2m paragraph 23, line 7-10). Winterton, et al further teaches that in addition to polyionic materials, various other materials and/or additives can be applied to the device, such as antimicrobials and antibacterials (see page 2, paragraph 19, lines 1-5).

The teachings of Winterton, et al; however do not teach the lens material made of a silicone containing hydrogel. As evidenced by the teachings of Sakuma, et al, contact lenses are commonly made using a silicone containing hydrogel. Sakuma, et al teaches a contact lens material that prevents breeding of bacteria to protect the cornea (see column 1, line 37-39), where the lens is a hydrogel lens material with ceramics uniformly dispersed in the hydrogel material, such as silica-based ceramics, which includes silicone (see column 1, lines 53-56). Sakuma, et al further teaches the ceramics as mentioned have the property of inorganic ion exchange; hence the antibacterial ceramics in the invention can be easily prepared by the ion exchange method.

The teaching of Sakuma, et al motivates or suggests the combining of its teachings along with Winterton, et al to result in the claimed invention of the independent instant claim 1 (b).

It would have been prima facie obvious to one skilled in the art, at the time of the invention to use a silicone containing hydrogel for a medical device, as evidenced by Sakuma et al, that has an oppositely charged polyionic LbL layer or antimicrobial LbL layer that is not covalently attached, as evidenced by Winterton, et al.

Response to Arguments

Applicant's arguments filed 02/01/08 have been fully considered but they are not persuasive. Applicant argues that a prima facie case of obvious has not been established, because the primary reference, alone or in combination with the secondary reference, does not disclose or suggest all of the limitations of the invention as currently claimed. The primary reference discloses that a method of forming a contact lens within a mold is provided. A coating of a polyionic material(s) is applied to the mold before forming a lens therein (abstract). In contrast, the present invention teaches that a contact lens comprising a core material which is a silicone-containing hydrogel material and an antimicrobial LbL coating that is not covalently attached to the core material. The secondary reference (US Patent No. 5213801 to Sakuma et al.) cannot fill the gaps left by the primary reference.

These arguments are not persuasive since instant claims are drawn to a lens itself, not the method of making. Winterton clearly teaches polyanionic and polycationic material (see paragraph [0098]). Furthermore, Winterton teaches any material used in the art to form polymeric materials, such as contact lenses, can be used (see paragraph [0012]). Therefore, one of ordinary skill in the art would be motivated to use silicone, as taught in Sakuma as polymeric material.

2. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton, et al and Sakuma et al in further view of US Patent No. 4933410 to Okrongly.

See above 103(a) rejection. The teachings of Winterton, et al and Sakuma, et al teach the medical device comprising a core material which is a silicone containing hydrogel material with

an antimicrobial LbL coating that is not covalently attached, and may have an oppositely charged polyionic LbL layer. These teachings; however, do not describe that the antimicrobial peptides are covalently attached to the LbL coating through the reactive sites, as disclosed in claim 1 (a).

The teaching of Okrongly teaches covalent attachment of macromolecules on substrate surfaces. Okrongly teaches formed substantially un-crosslinked polystyrene products are functionalized employing hydroxymethylamides for electrophillic substitution of the phenyl groups. The resulting polystyrene may be used for reacting with a wide variety of functionalities, particularly associated with macromolecules; to provide for a high density of covalently bonded macromolecules (column 2, line 3-15). The solid substrate may exist in any form, including, but not limited to reaction vessels, microtiter plates, membranes, and so on (column 2, line 48-55). Okrongly further teaches the groups that may be substituted onto the polystyrene material include, but are not limited to proteins, particularly biologically active proteins, and peptides (column 5, line 21-43).

This third teaching of Okrongly motivates or suggests the combining of its teachings along with Winterton et al and Sakuma et al, to result in the claimed invention of the independent instant claim 1 (a).

It would have been prima facie obvious to one skilled in the art, at the time of the invention to use the covalent bonding process as evidenced by Okrongly, et al, to covalently bind antimicrobial peptides to a medical device, such as an LbL polyionic bi-layer and LbL antimicrobial contact lens, as evidenced by Winterton, et al and Sakuma et al, to create a medical device which has the antimicrobial benefits as disclosed in the instant application because

covalent attachment is well known to be resistant to washing, which is common in contact lens use.

Response to Arguments

Applicant's arguments filed 02/01/08 have been fully considered but they are not persuasive. Applicant argues the third reference; Okrongly does not disclose the antimicrobial peptides are covalently attached to the LbL coating through the reactive sites as the currently amended claimed 1 recited. Please note that LbL coating is not functionalized polystyrene as required by the invention of the third reference Okrongly.

These arguments are not persuasive since Okrongly teaches the principle of functionalizing the surface for attachment of various proteins. The principle will be the same whether the protein is attached to polystyrene or any material.

3. Claims 2, 3, and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton, et al and Sakuma et al, as applied to claim 1 b), above, and further in view of Diaz-Achirica, et al.

See above 103(a) rejection, for claim 1 (b). The teachings of Winterton, et al and Sakuma, et al teach to use a silicone containing hydrogel for a medical device, that has an oppositely charged polyionic LbL layer or antimicrobial LbL layer that is not covalently attached.

Winterton, et al further teaches that the polycationic material used in their invention can generally include any material known in the art to have a plurality of positively charged groups along a polymer chain; suitable polycationic materials can include, but are not limited to poly(allylamine hydrochloride) (PAH), (see page 5, paragraph 63 and 64). In addition,

Winterton, et al, teaches a polyanionic material used in their invention can generally include any material known in the art to have a plurality of negatively charged groups along a polymer chain; suitable polycationic materials can include, but are not limited to polyacrylic acid (PAA) (see page 6, paragraph 70 and 72).

Winterton, et al and Sakuma et al; however, do not teach that cecropin – A – melitin hybrid is in the main family of antimicrobial peptides which are present in insect hemolymph (see page 1, column 1, paragraph 2), as taught in Diaz-Achirica, et al. Diaz-Achirica, et al goes on to teach that cecropin and melitin have been shown to form channels and permeabilize biological membranes as part of their mechanism of action; furthermore, the synthesis of cecropin-melitin hybrid peptides have been proven to be a useful approach for the design of more potent antibacterial peptides with broader specificity against pathogens, while avoiding the toxic effects on eukaryotic cell types (pages 2-3, results, bridging paragraph 1).

This third teaching of Diaz-Achirica et al, motivates of suggests the combining of its teachings along with Winterton, et al and Sakuma et al, to result in the claimed invention of the instant claims 2, 3, and 8-10.

It would have been prima facie obvious to one skilled in the art, at the time of the invention, to combine the teachings of Winterton, et al, and Sakuma et al, along with Diaz-Achirica, et al, to use a silicone containing hydrogel for a medical device, as evidenced by Sakuma et al, that has an oppositely charged polyionic LbL layer or antimicrobial LbL layer that is not covalently attached, as evidenced by Winterton, et al, which, furthermore, has an antimicrobial peptide layer of cecropin – A – melitin hybrid as the antimicrobial agent for the medical device disclosed in the instant application.

Response to Arguments

Applicant's arguments filed 02/01/08 have been fully considered but they are, once again, not persuasive. Applicant's arguments pertain to method of forming lenses. These have been discussed above in the first 103(a) rejection.

4. Claims 2, 4, 5, 6, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winterton, et al, Sakuma et al, and Okrongly as applied to claim 1(a) above, and further in view of the Diaz-Achirica, et al.

See above 103(a) rejection for claim 1(a). The above references teach the use the covalent bonding process as evidenced by Okrongly, et al, to covalently bind antimicrobial peptides to a medical device, such as an LbL polyionic bi-layer and LbL antimicrobial contact lens, as evidenced by Winterton, et al and Sakuma et al, to create a medical device which has the antimicrobial benefits as disclosed in the instant application.

These teachings, however, do not teach that cecropin – A – melitin hybrid is in the main family of antimicrobial peptides which are present in insect hemolymph (see page 1, column 1, paragraph 2), as taught in Diaz-Achirica, et al. Diaz-Achirica, et al goes on to teach that cecropin and melitin have been shown to form channels and permeabilize biological membranes as part of their mechanism of action; furthermore, the synthesis of cecropin-melitin hybrid peptides have been proven to be a useful approach for the design of more potent antibacterial peptides with broader specificity against pathogens, while avoiding the toxic effects on eukaryotic cell types (pages 2-3, results, bridging paragraph 1).

This fourth teaching of Diaz-Achirica et al, motivates of suggests the combining of its teachings along with Winterton, et al Sakuma et al, and Okrongly to result in the claimed invention of the instant claims 2, 4, 5, 6 and 16-18.

It would have been prima facie obvious to one skilled in the art, at the time of the invention, to combine the teachings of Winterton, et al, Sakuma et al, and Okrongly, along with Diaz-Achirica, et al, to use a silicone containing hydrogel for a medical device, as evidenced by Sakuma et al, that has an oppositely charged polyionic LbL layer or antimicrobial LbL layer that is not covalently attached, as evidenced by Winterton, et al, which, furthermore, has an antimicrobial peptide layer of cecropin – A – melitin hybrid as the antimicrobial agent for the medical device disclosed in the instant application.

Response to Arguments

Applicant's arguments filed 02/01/08 have been fully considered but they are not persuasive. Examiner has addressed Applicant's arguments with respect to Winterton, Sakuma and Okrongly. Applicants argue the fourth reference (Diaz-Achirica, et al.) do not disclose the antimicrobial peptides are covalently attached to the LbL coating through the reactive sites as the currently amended claims recited. Please note that LbL coating is not functionalized polystyrene as required by the invention of the third reference (Okrongly).

These arguments are found non persuasive. An examiner point out the teachings of Diaz-Achirica, et al. is combined for its teachings of cercropin-A (claimed antimicrobial peptide) and the principle of attachment of proteins in respect to the nature of the proteins.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAHRZAD SPIELER whose telephone number is (571)270-1557. The examiner can normally be reached on Weekly 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

SS